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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 9

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Application Number 10/042,203
Filing Date January 11, 2002
First Named Inventor Bernd RIEDL et al.
Group Art Unit 1625
Examiner Name Rita J. Desai
Attorney Docket Number BAYER-25A

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
RP	A1	2002/017507	A1	Santora et al.	11-21-2002
	A2	2002/0065283	A1	McMahon et al.	05-30-2002
	A3	2002/0065296	A1	Dumas et al.	05-30-2002
	A4	2004/0209905	A1	Kubo et al.	10-21-2004
	A5	5063247		Sekiya et al.	11-05-1991
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	A7	5658903		Adams et al.	08-19-1997
	A8	5710094		Minami et al.	01-20-1998
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	A10	5808080		Bell et al.	09-15-1998
	A11	6297381	B1	Cirillo et al.	10-02-2001
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	A13	6329415	B1	Cirillo et al.	12-11-2001
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	A15	6372773	B1	Regan	04-16-2002
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	A17	6525046	B1	Cirillo et al.	02-25-2003
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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
RP	B1	WO	02/14311	A2	Amgen Inc.	02-21-2002		
	B2	WO	02/32872	A1	Eisai Co. Ltd.	04-25-2002		
	B3	WO	02/44158	A1	Pfizer Products Inc.	06-06-2002		
	B4	WO	02/07772	A2	Boehringer Ingelheim	01-31-2002		
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R. Desai

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	B26	WO	2005/048948	A2	Ambit Biosciences	06-02-2005		
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Application Number	10/042,203
Filing Date	January 11, 2002
First Named Inventor	Bernd RIEDL et al.
Group Art Unit	1625
Examiner Name	Rita J. Desai
Attorney Docket Number	BAYER-25A

FOREIGN PATENT DOCUMENTS (cont'd.)

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		Office ²	Number ³	Kind Code ⁵ (if known)				
Ro	B38	WO	01/07411	A1	Banyu Pharmaceutical	02-01-2001		
Rp	B39	UK	1110099		Julia	06-07-1966		
Ro	B40	WO	2004078746	A2	Boyer et al.	09-16-2004		
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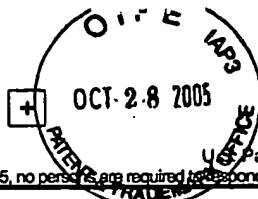
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/042,203
				Filing Date	January 11, 2002
				First Named Inventor	Bernd RIEDL et al.
				Group Art Unit	1625
				Examiner Name	Rita J. Desai
Sheet	4	of	9	Attorney Docket Number	BAYER-25A

FOREIGN PATENT DOCUMENTS (cont'd.)								
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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
ro	B68	WO	9962890	A1	Larson et al.	12-09-1999		
	B69	WO	0109088	A1	Padia et al.	02-08-2001		
	B70	WO	0214281	A1	Cochran et al.	02-21-2002		
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	B84	EP	1199306	A1	Hayama et al.	04-24-2002		
ro	B85	EP	0709225	B1	Minami et al.	08-05-1998		

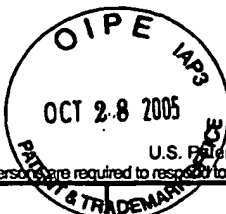
NON PATENT LITERATURE DOCUMENTS			
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ro	C1	Nickel et al., "Carboxylic acid analogues of suramin, potential filaricides," <i>Indian Journal of Chemistry</i> , Vol. 30B, February 1991, p. 182-187	
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Examiner Signature	<i>R. Desai</i>	Date Considered	1/17/06
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<i>pd</i>	C6	Internal Medicine, 4 th Edition, 1994, pp. 699-715	
	C7	Johannes L. Bos, "Ras oncogenes in human cancer: a review," <i>Cancer Research</i> , 49, 4682-4689, September 1, 1989	
	C8	Kempton et al., "Synthese potentieller Pflanzenschutz- und Schädlingsbekämpfungsmittel aus substituierten Anilinen," Pädagogische Hochschule, Eingegangen am 1.7.1982, 101-120	
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	C16	Sorbara et al., "BAY-43-9006," <i>Drugs of the Future</i> , 2002, 27(12):1141-1147	
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Signature

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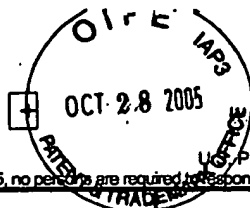
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R	C21	Strumberg et al., "Results of phase I pharmacokinetic and pharmacodynamic studies of the raf kinase inhibitor BAY 43-9006 in patients with solid tumors," <i>International Journal of Clinical Pharmacology and Therapeutics</i> , Vol. 40, No. 12/2002 (580-581)	
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	C24	Auclair, et al., "BAY 43-9006 (Sorafenib) is a potent inhibitor of FLT3 tyrosine kinase signaling and proliferation in AML cells," 96 th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	
	C25	Murphy et al., "BAY 43-9006 controls tumor growth through inhibition of vascular development," 96 th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	
	C26	Spronsen et al., "Novel treatment strategies in clear-cell metastatic renal cell carcinoma," <i>Anti-Cancer Drugs</i> , 2005, 16:709-717	
	C27	Thaimattam et al., "3D-QSAR CoMFA, CoMSIA studies on substituted ureas as Raf-1 kinase inhibitors and its confirmation with structure-based studies," <i>Bioorganic & Medicinal Chemistry</i> , 12(2004) 6415-6425	
	C28	Danson et al., "Improving outcomes in advanced malignant melanoma," <i>Drugs</i> , 2005, 65(6):733-743	
	C29	Heim et al., "Antitumor effect and potentiation or reduction in cytotoxic drug activity in human colon carcinoma cells by the Raf kinase inhibitor (RKI) BAY 43-9006," <i>International Journal of Clinical Pharmacology and Therapeutics</i> , Vol. 41, No. 12/2003 (616-617)	
	C30	Richly et al., "Results of a phase I trial of BAY 43-9006 in combination with doxorubicin in patients with primary hepatic cancer," <i>International Journal of Clinical Pharmacology and Therapeutics</i> , Vol. 42, No. 11/204 (650-651)	
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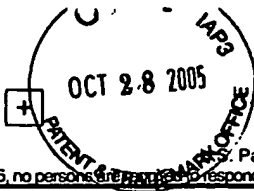
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/042,203
		Filing Date	January 11, 2002
		First Named Inventor	Bernd RIEDL et al.
		Group Art Unit	1625
		Examiner Name	Rita J. Desai
		Attorney Docket Number	BAYER-25A
Sheet	7	of	9

NON PATENT LITERATURE DOCUMENTS (cont'd.)			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
RP	C33	DeGrendele, "Activity of the raf kinase inhibitor BAY 43-9006 in patients with advanced solid tumors," <i>Clinical Colorectal Cancer</i> , May 2003, pp. 16-18	
	C34	Hubbard, "Oncogenic mutations in B-Raf: some losses yield gains," Skirball Institute of Biomolecular Medicine and Department of Pharmacology, New York University School of Medicine, New York, NY	
	C35	Thompson et al., "Recent progress in targeting the Raf/MEK/ERK pathway with inhibitors in cancer drug discovery," <i>Curr. Opin. Pharmacol.</i> , 2005 Aug., 5(4):350-6	
	C36	Moore et al., "Phase I study to determine the safety and pharmacokinetics of the novel Raf kinase and VEGFR inhibitor BAY 43-9006, administered for 28 days on/7 days off in patients with advanced, refractory solid tumors," <i>Annals of Oncology</i> , 16:1688-1694, 2005	
	C37	Ahmad et al., "Kinase inhibition with BAY 43-9006 in renal cell carcinoma," <i>Clinical Cancer Research</i> , Vol. 10, 6388s-6392s, 15 Sept. 2004	
	C38	Wan et al., "Mechanism of activation of the RAF-ERK signaling pathway by oncogenic mutations of B-RAF," <i>Cell</i> , Vol. 116, 855-867, 19 March 2004	
	C39	Hanson, "Pulmonary-Allergy, Dermatological, Gastrointestinal & Arthritis, Inhibitors of p38 kinase," <i>Exp. Opin. Ther. Patents</i> , (1997) 7(7):729-733	
	C40	Strumberg et al., "Phase I clinical and pharmacokinetic study of the novel raf kinase and vascular endothelial growth factor receptor inhibitor BAY 43-9006 in patients with advanced refractory solid tumors," <i>Journal of Clinical Oncology</i> , Vol. 23, No. 5, 10 Feb. 2005, 965-972	
	C41	Regan et al., "Pyrazole urea-based inhibitors of p38 MAP kinase: from lead compound to clinical candidate," <i>J. Med. Chem.</i> , 2002, 45, 2994-3008	
	C42	Clark et al., "Safety and pharmacokinetics of the dual action raf kinase and vascular endothelial growth factor receptor inhibitor, BAY 43-9006, in patients with advanced, refractory solid tumors," <i>Clin. Cancer Res.</i> , 2005:11(15), 1 August 2005, 5472-5480	
	C43	Wilson et al., "The structural basis for the specificity of pyridinylimidazole inhibitors of p38 MAP kinase," <i>Chemistry & Biology</i> , 1997, Vol. 4, No. 6, 423-431	
	C44	Hotte et al., "BAY 43-9006: early clinical data in patients with advanced solid malignancies," <i>Current Pharmaceutical Design</i> , 2002, 8, 2249-2253	
	C45	Jeffcoat et al., "The metabolism and toxicity of halogenated carbanilides," <i>Drug Metabolism and Deposition</i> , Vol. 5, No. 2, 157-166	
RP	C46	Murata et al., "Facile synthesis of new pyrrolo[3,4-d]pyrimidine-2,4-diones," <i>Chem. Pharm. Bull.</i> , 22(5) 1212-1213 (1974)	

Examiner Signature		Date Considered	1/17/06
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<i>R</i>	C47	Yasuo et al., "Intra-arterial ACNU, CDDP chemotherapy for brain metastases from lung cancer: comparison of cases with and without intra-arterial mannitol infusion," <i>Neurol. Surg.</i> , (1993) vol. 21, no. 6, pp. 513-518	
	C48	Murata et al., "Facile synthesis of new pyrrolo[3,4-d]pyrimidine-2,4-diones," <i>Chemical & Pharmaceutical Bulletin</i> , (1974), 22(5):1212-13	
	C49	Hanson, "Inhibitors of p38 kinase," <i>Expert Opinion on Therapeutic Patents</i> , July 1997, vol. 7, no. 7, pp. 729-733(5)	
	C50	Garcia-Lopez et al., "New routes for the synthesis of pyrrolo[3,2-d]- and -[2,3-d]pyrimidine systems starting from a common pyrrole derivative," <i>Journal of the Chemical Society, Perkin Transactions 1: Organic and Bio-Organic Chemistry</i> (1972-1999) (1978), (5), 483-7	
	C51	Wilhelm et al., "BAY 43-9006: preclinical data," <i>Curr Pharm Des</i> , 2002, 8(25):2255-7	
	C52	Wright et al., "Clinical trials referral resource. Current clinical trials of BAY 43-9006, Part 1," <i>Oncology</i> , 2005 Apr, 19(4):499-502	
	C53	Dumas, "Protein kinase inhibitors from the ureas class," <i>Current Opinion in Drug Discovery & Development</i> , 2002, Vol. 5, No. 5, 718-727	
	C54	Patent Abstracts of Japan, Publication No. 02-023337, published 01-28-1990	
	C55	Patent Abstracts of Japan, Publication No. 02-022650, published 01-25-1990	
	C56	Wisner et al., "Analogues of platelet activating factor. 7. Bis-aryl amide and bis-aryl urea receptor antagonists of PAF," <i>J. Med. Chem.</i> , 1992, 35, 4779-4789	
	C57	Ravi et al., "Activated raf-1 causes growth arrest in human small cell lung cancer cells," <i>J. Clin. Invest.</i> , pp. 153-159	
	C58	Lemoine, "Overview of ras oncogenes and their clinical potential," Chapter 10,	
	C59	<i>Drug, facts and comparisons</i> , 1994 Edition, pp. 2703-2705	
	C60	Siu et al., "Phase I study of oral raf-1 kinase inhibitor BAY 43-9006 with gemcitabine in patients with advanced solid tumors," <i>Proc Am Soc Clin Oncol</i> , 22:207, 2003 (abstr 828)	
	C61	Escudier et al., "Randomized phase III trial of the raf kinase and VEGFR inhibitor sorafenib (BAY 43-9006) in patients with advanced renal cell carcinoma (RCC)," Meeting: 2005 ASCO Annual Meeting, Category: Genitourinary Cancer, Subcategory: Kidney Cancer, Abstract No. 4510	
<i>R</i>	C62	Eisen et al., "Phase I trial of BAY 43-9006 (sorafenib) combined with dacarbazine (DTIC) in metastatic melanoma patients," Meeting: 2005 ASCO Annual Meeting, Category: Melanoma, Subcategory: Melanoma, Abstract No. 7508	

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Signature

R. Desai

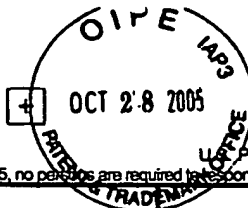
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RP	C63	Adjei et al., "A phase I study of BAY 43-9006 and gefitinib in patients with refractory or recurrent non-small-cell lung cancer (NSCLC)," Meeting: 2005 ASCO Annual Meeting, Category: Developmental Therapeutics: Molecular Therapeutics, Subcategory: Antiangiogenic or Antimetastatic agents, Abstract No. 4510	
	C64	Carling et al., "1-(3-cyanobenzylpiperidin-4-yl)-5-methyl-4-phenyl-1,3-dihydroimidazol-2-one: A selective high-affinity antagonist for the human dopamine D ₄ receptor with excellent selectivity over ion channels," <i>J. Med. Chem.</i> , 1999, 42, 2706-2715	
	C65	Van Muijlwijk-Koezen et al., "Isoquinoline and quinazoline urea analogues as antagonists for the human adenosine A ₃ receptor," <i>J. Med. Chem.</i> , 2000, 43, 2227-2238	
	C66	Eisenhauer et al., "Impact of new non-cytotoxics in the treatment in ovarian cancer," <i>Int. J. Gynecol Cancer</i> , 2001, 11 (Suppl. 1), 68-72	
	C67	Kubo et al., "Synthesis and structure-activity relationship of quinazoline-urea derivatives as novel orally active VEGF receptor tyrosine kinase selective inhibitors," #913, XP-001152608	
	C68	Carter et al, "Anti-tumor efficacy of the orally active raf kinase inhibitor BAY 43-9006 in human tumor xenograft models," #4954, XP-001145482	
	C69	Strumberg et al., "Phase I and pharmacokinetic study of the raf kinase inhibitor bay 43-9006 in patients with locally advanced or metastatic cancer," #2921, XP-001145481	
	C70	Dumas et al., "1-phenyl-5-pyrazolyl ureas: potent and selective p38 kinase inhibitors," <i>Bioorganic & Medicinal Chemistry Letters</i> , 10 (2000), 2051-2054	
	C71	Riedl et al., "Potent raf kinase inhibitors from the diphenylurea class: structure activity relationships," #4956, XP-001145518	
	C72	Iwadate et al., "Intra-arterial ACNU, CDDP chemotherapy for brain metastases from lung cancer: comparison of cases with and without intra-arterial mannitol infusion," Dept of Neurological Surgery, Chiba Cancer Center Hospital, Clinical Trial, Journal Article, Randomized Controlled Trial, Vol. 21, No. 6, 513-518	
	C73	Geiger et al., "Antitumor activity of a C-raf antisense oligonucleotide in combination with standard chemotherapeutic agents against various human tumors transplanted subcutaneously into nude mice," <i>Clinical Cancer Research</i> , Vol. 3, 1179-1185, July 1997	
fe	C74	Cunningham et al., "A phase I trial of H-ras antisense oligonucleotide ISIS 2503 administered as a continuous intravenous infusion in patients with advanced carcinoma," <i>Cancer</i> , September 2001, Vol. 92, No. 5, 1265-1271	

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